Proposed Decision Memo for Cardiac Rehabilitation Programs (CAG-00089R)

Decision Summary

Decision Summary
The Centers for Medicare and Medicaid Services (CMS) proposes the following:
The evidence is adequate to conclude that cardiac rehabilitation is reasonable and necessary following acute myocardial infarction (AMI), coronary artery bypass graft (CABG), stable angina pectoris, heart valve repair/replacement, percutaneous transluminal coronary angioplasty (PTCA), and heart or heart lung transplant
CMS has determined that the evidence is not adequate to conclude that cardiac rehabilitation is reasonable and necessary for congestive heart failure, and therefore we will not cover this indication.
CMS proposes revising the language in Manual 100-3 § 20.10 to read as follows:
A – Item/Service Description
Phase II cardiac rehabilitation, as described by the U.S. Public Health Service is a comprehensive, long-term program including medical evaluation, prescribed exercise, cardiac risk factor modification, education and counseling. Phase II refers to outpatient medically supervised programs that are typically initiated 1-3 weeks after hospital discharge and provide appropriate ECG monitoring.
B – Indications and Limitations of Coverage

Medicare coverage of cardiac rehabilitation programs are considered reasonable and necessary only for patients
who (1) have a documented diagnosis of acute myocardial infarction within the preceding 12 months; or (2) have
had coronary bypass surgery; or (3) have stable angina pectoris; or (4) have had heart valve
repair/replacement; or (5) have had percutaneous transluminal coronary angioplasty (PTCA); or (6) have had
heart or heart lung transplant.

C - Program Requirements

1. Duration

Services provided in connection with a cardiac rehabilitation exercise program may be considered reasonable and necessary for up to 36 sessions without individual review by a contractor's medical consultant. Patients generally receive 2 to 3 sessions per week for 12 to 18 weeks. Claims for cardiac rehabilitation services beyond 18 weeks should be reviewed by the contractors' medical consultants to determine if coverage should be extended but not exceed a total of 72 sessions for 36 weeks.

2. Components

Cardiac rehabilitation programs must be comprehensive and to be comprehensive they must include a medical evaluation, a program to modify cardiac risk factors (e.g., nutritional counseling), prescribed exercise, education and counseling.

3. Facility

The facility must have available for immediate use the necessary cardio-pulmonary emergency diagnostic and therapeutic life saving equipment accepted by the medical community as medically necessary, e.g., oxygen, cardiopulmonary resuscitation equipment, or defibrillator.

4. Staff

The program must be staffed by personnel necessary to conduct the program safely and effectively, who are trained in both basic and advanced life support techniques and in exercise therapy for coronary disease. The program must be under the direct supervision of a physician, as defined in 42 C.F.R. § 410.26(a)(2) (defined through cross reference to 42 C.F.R. § 410.32(b)(3)(ii), or 42 C.F.R. § 410.27(f)).

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Proposed Decision Memo

TO: Administrative File: CAG 00089R

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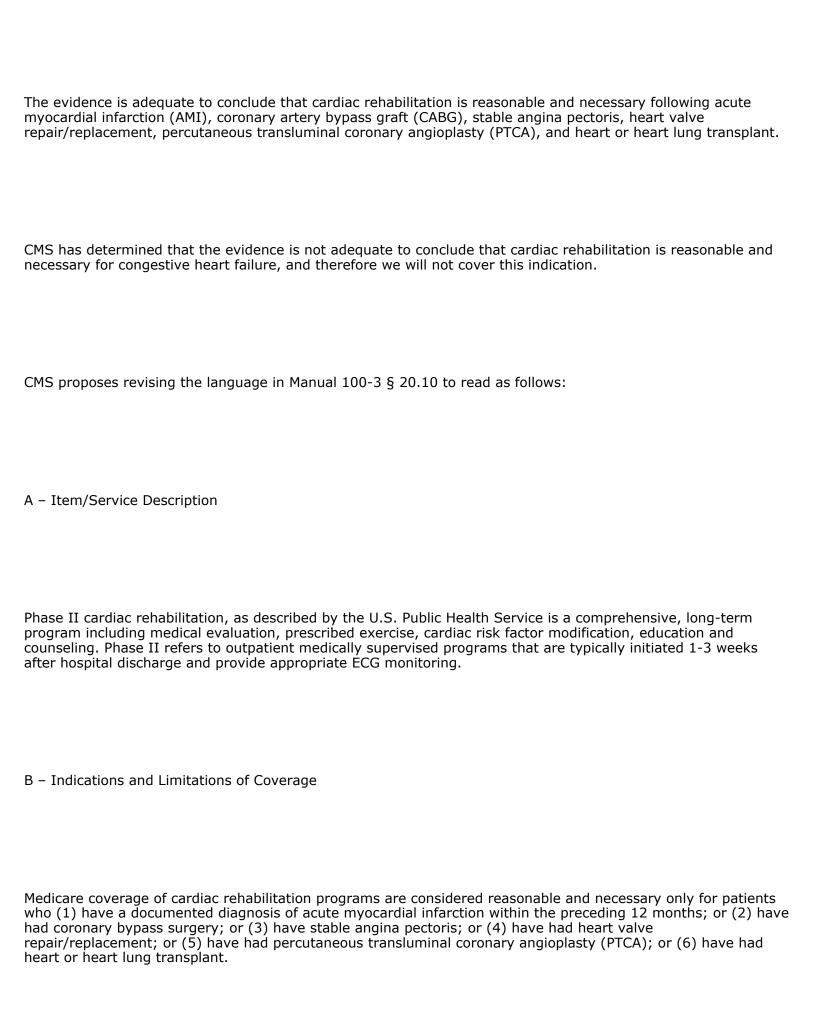
SUBJECT: Proposed Coverage Decision Memorandum for Cardiac Rehabilitation

DATE: December 22, 2005

I. Proposed Decision

The Centers for Medicare and Medicaid Services (CMS) proposes the following:

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C – Program Requirements

Duration

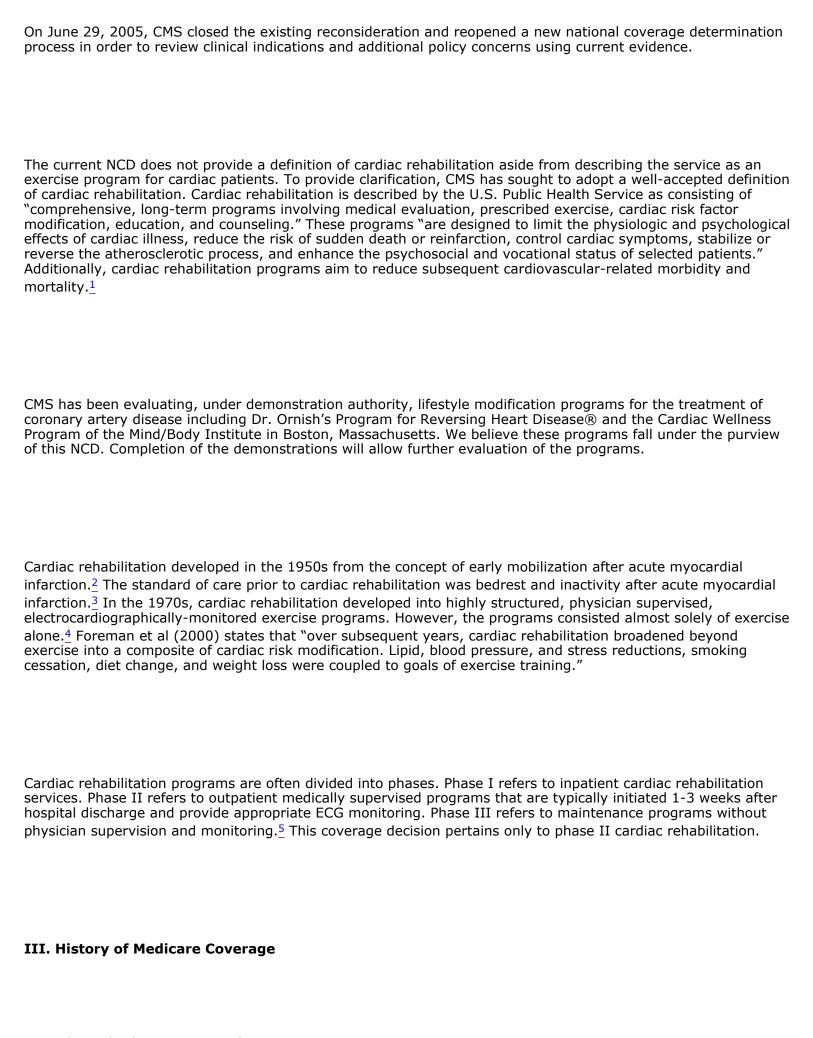
Services provided in connection with a cardiac rehabilitation exercise program may be considered reasonable and necessary for up to 36 sessions without individual review by a contractor's medical consultant. Patients generally receive 2 to 3 sessions per week for 12 to 18 weeks. Claims for cardiac rehabilitation services beyond 18 weeks should be reviewed by the contractors' medical consultants to determine if coverage should be extended but not exceed a total of 72 sessions for 36 weeks.

- 2. Components
 - Cardiac rehabilitation programs must be comprehensive and to be comprehensive they must include a medical evaluation, a program to modify cardiac risk factors (e.g., nutritional counseling), prescribed exercise, education and counseling.
- 3. Facility
 - The facility must have available for immediate use the necessary cardio-pulmonary emergency diagnostic and therapeutic life saving equipment accepted by the medical community as medically necessary, e.g., oxygen, cardiopulmonary resuscitation equipment, or defibrillator.
- Staff
 - The program must be staffed by personnel necessary to conduct the program safely and effectively, who are trained in both basic and advanced life support techniques and in exercise therapy for coronary disease. The program must be under the direct supervision of a physician, as defined in 42 C.F.R. § 410.26(a)(2) (defined through cross reference to 42 C.F.R. § 410.32(b)(3)(ii), or 42 C.F.R. § 410.27(f)).

II. Background

On February 20, 2001, CMS internally generated a formal national coverage request for supervised cardiac rehabilitation to determine if literature supports the clinical effectiveness of four additional indications; (1) heart valve repair or replacement; (2) coronary angioplasty; (3) heart or heart/lung transplant; and (4) congestive heart failure. CMS then requested, on November 5, 2001, that the Office of the Inspector General assist CMS in determining whether outpatient cardiac rehabilitation programs meet the existing physician supervision requirement. Upon receipt of the OIG's report, CMS intended to announce a new completion date for the NCD. The report resulted in a recommendation to CMS from the OIG to revise the policy to provide needed clarification. CMS had separately received similar recommendations from providers that the policy be more straightforward in addition to their requesting that the policy be revised to reduce the burden required to be compliant with the current policy.

In January 2005, CMS held a meeting of the Medicare Coverage Advisory Committee entitled *Physician-supervised behavioral interventions for patients with symptomatic coronary artery disease.* Information regarding this meeting is provided under the *MCAC* subheading in section VII(B)(4) of this document.



History of Medicare Coverage of Cardiac Rehabilitation
Since 1982, Medicare's national coverage decision has provided for phase II cardiac rehabilitation for patients who experience stable angina, have had coronary artery bypass grafts, or have had an acute myocardial infarction within the past twelve months. There have been two modifications to the policy since 1982.
The first change, issued in December 1985, clarified the payment limitation applying to freestanding clinics and the policy regarding physical therapy and occupational therapy services. The second modification, issued in August 1989, was in response to CMS's Technology Advisory Group's (TAG) clarification of physician supervision In 1988, the TAG defined the necessary level of supervision to be that the physician must be present on the immediate premises, but not necessarily in the room.
Current Medicare National Coverage Decision Regarding Cardiac Rehabilitation
The National Coverage Determination Manual (manual 100-3) addresses Medicare's national coverage decision for cardiac rehabilitation in §20.10. The current Medicare national coverage decision limits coverage to only phase II cardiac rehabilitation for patients who (1) have a documented diagnosis of acute myocardial infarction within the preceding 12 months; or (2) have had coronary bypass surgery; and/or (3) have stable angina pectoris. Under the current policy, no other diagnostic categories may be covered. Contractors do not currently have the discretion to extend coverage beyond these indications. Under current policy, phase II cardiac rehabilitation programs may be provided under physician supervision either by the outpatient department of a hospital or in a physician-directed clinic.
Benefit Category

For an item or service to be covered by the Medicare program, it must meet one of the statutorily defined benefit categories outlined in the Social Security Act. Cardiac rehabilitation falls under the benefit category set forth in section 1861(s)(2)(A) of the Social Security Act (services incident to a physician's professional service). For Part B, services must be an integral, though incidental, part of the service of a physician in the course of diagnosis or treatment of an injury or illness (42 CFR 410.26(b)(2)). Medicare Part B also pays for hospital services and supplies furnished incident to a physician service to outpatients if they are furnished by or under arrangements made by a participating hospital as an integral though incidental part of a physician's services (42 CFR 410.27(a)). In the case of cardiac rehabilitation, the ordering physician is the "incident to" physician.

IV. Timeline of Recent Activities

February 20, 2001	CMS internally generates a formal national coverage request for supervised cardiac rehabilitation to evaluate whether literature supports the clinical effectiveness of physician supervised cardiac rehabilitation for the following additional indications: (1) heart valve repair or replacement; (2) coronary angioplasty; (3) heart or heart/lung transplant; and (4) congestive heart failure.
November 5, 2001	CMS requests that the Office of the Inspector General assist CMS in determining whether outpatient cardiac rehabilitation programs meet the current physician supervision requirements as outlined in the existing coverage policy. A new due date will be announced after CMS has received the OIG's report.
January 25, 2005	Medicare Coverage Advisory Committee meeting is held to discuss the evidence for Supervised Behavioral Interventions for Patients with Symptomatic Coronary Artery Disease.
June 15, 2005	CMS requests that the Agency for Healthcare Research and Quality (AHRQ) expand a previous technology assessment (available at http://www.cms.hhs.gov/mcac/id144a.pdf) to examine the components of cardiac rehabilitation programs.
June 29, 2005	Due to the length of time this reconsideration was pending, CMS closes the analysis without changing coverage for cardiac rehabilitation programs and opens a new reconsideration to review clinical indications and additional policy concerns using current evidence. At this time CMS requests public comment.

August 18, 2005	OIG issues final report.
December 12, 2005	AHRQ issues final report.

V. FDA Status

Cardiac rehabilitation is comprised of services that do not require FDA approval.

VI. General Methodological Principles

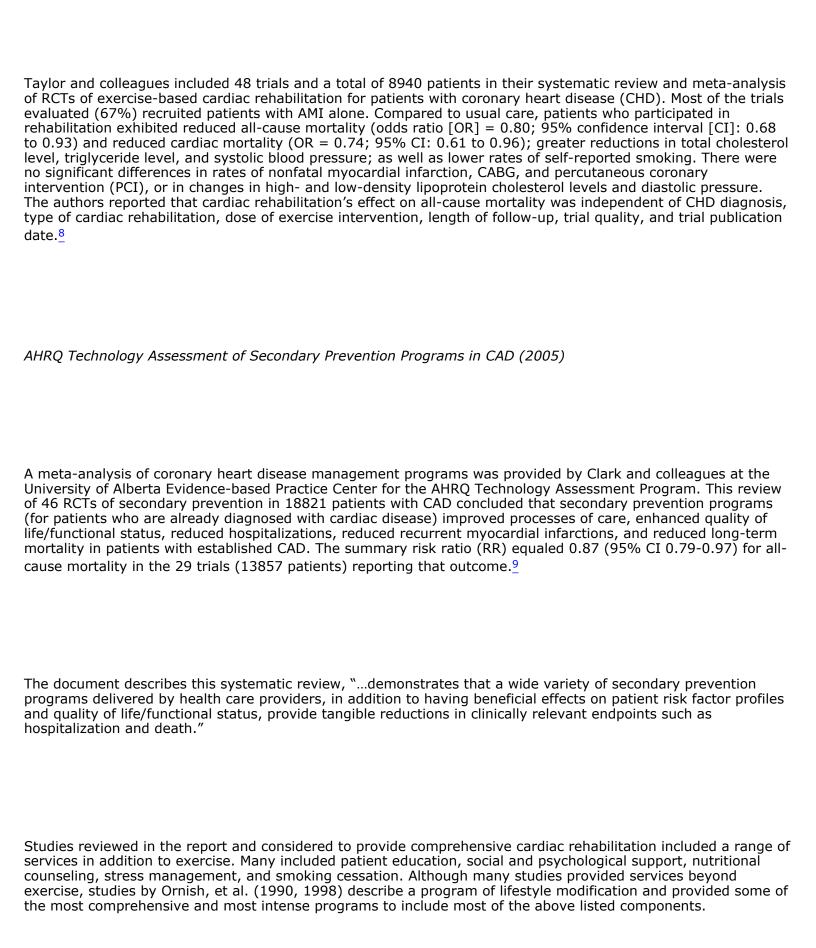
When making national coverage decisions, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding of whether an item or service is reasonable and necessary for the diagnosis and treatment of illness or injury. The evidence may consist of external technology assessments, internal review of published and unpublished studies, recommendations from the Medicare Coverage Advisory Committee, evidence-based guidelines, professional society position statements, expert opinion, and public comments.

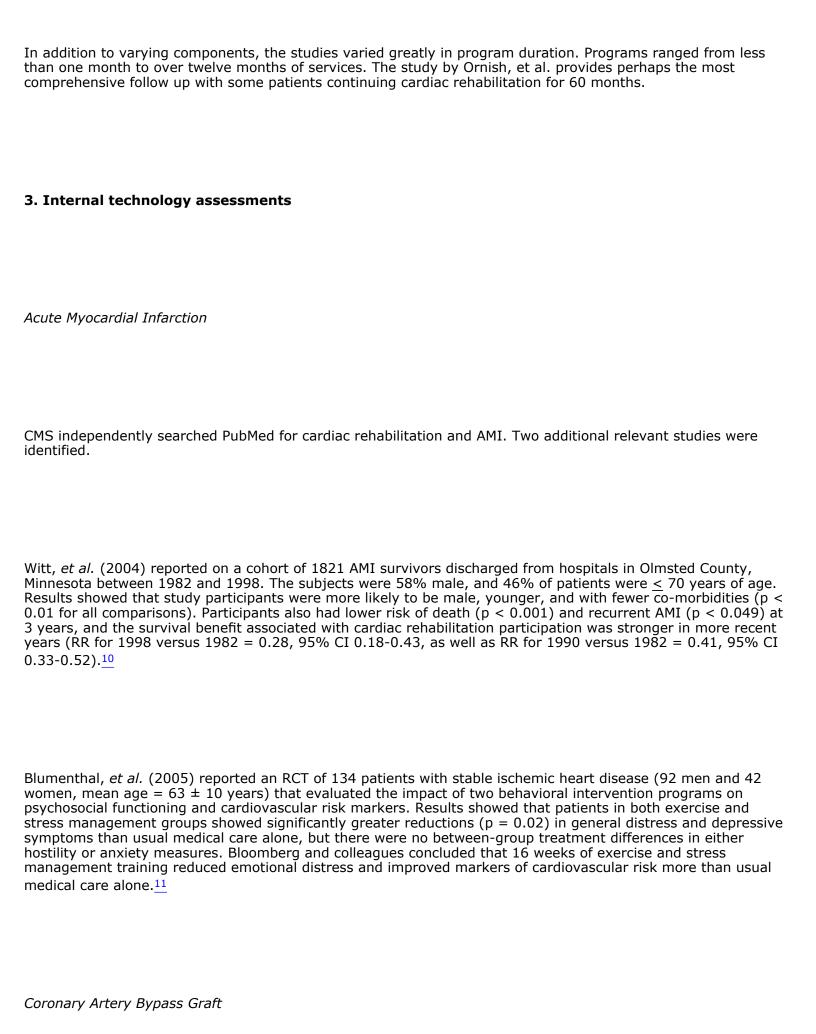
The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: (1) specific clinical questions relevant to the coverage request can be answered conclusively; and (2) the extent to which we are confident that the intervention will improve net health outcomes for patients. A fully detailed account of "General Methodological Principles of Study Design" that CMS staff utilizes to assess the relevant literature on the therapeutic or diagnostic item or service for specific conditions is available in Appendix A.

VII. Evidence
A. Introduction
This summary represents the body of evidence for cardiac rehabilitation following AMI, CABG, stable angina pectoris, heart valve repair/replacement, PTCA, heart or heart lung transplant, and congestive heart failure (CHF). Health outcomes of interest to CMS for these indications include changes in mortality, re-infarction or restenosis rates, modifiable risk factors, quality-of-life measures, and intermediate physiological outcomes. This National Coverage Analysis (NCA) focuses on the following question: "In persons age 65 years and older, what is the clinical evidence for a net health benefit from cardiac rehabilitation for the seven indications?"
B. Discussion of evidence reviewed
1. Literature Search
CMS searched the Cochrane Library, National Health Service Centre and International Network of Agencies for Health Technology Assessments databases for systematic reviews and technology assessments of cardiac rehabilitation. CMS similarly searched PubMed (1995 to present) for randomized clinical trials (RCTs) and observational studies evaluating cardiac rehabilitation for persons 65 years of age and older. General keywords included cardiac rehabilitation, core components, and secondary prevention. Studies must have presented origina data, included < 10 patients, examined primary health outcomes or intermediate physiological outcomes, and been published in peer-reviewed English language journals. Abstracts were excluded.
2. External technology assessments

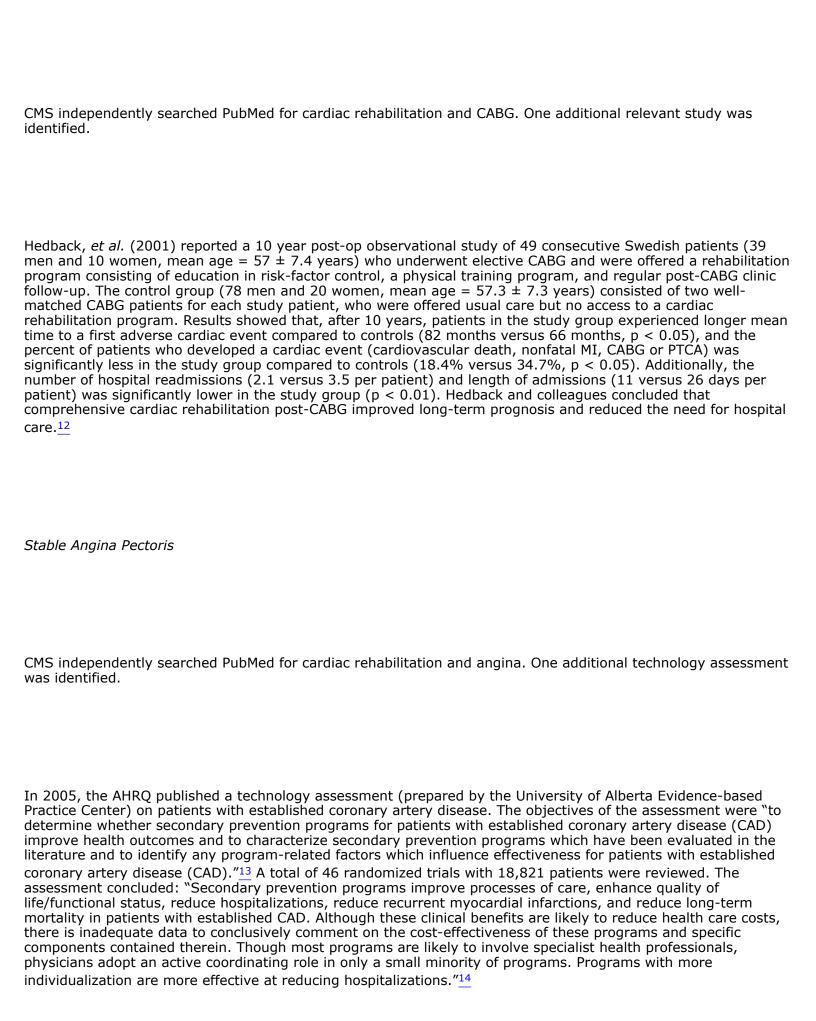
OHTA Report on Cardiac Rehabilitation Programs (1991)
The Agency for Healthcare Policy and Research (AHCPR) Office of Health Technology Assessment (OHTA) performed a technology assessment assessing the benefits of cardiac rehabilitation programs for patients following heart transplantation, PCTA or heart valve surgery. The report concluded that cardiac rehabilitation programs were safe and effective in improving functional activities of patients with cardiac disease, and that transplant, PTCA, or heart valve surgery patients had no unique characteristics differentiating them from AMI, CABG, or stable angina patients regarding necessity for cardiac rehabilitation.
NHS Centre for Reviews and Dissemination (1998)
The NHS bulletin identified over 200 reviews of cardiac rehabilitation. Evaluation was acknowledged to have been difficult "due to the variability of interventions and patient populations studied." The bulletin stated "exercise improves physical aspects of recovery at no additional risk, but as a sole intervention it is not sufficient to reduce risk factors, morbidity or mortality." Also noted was that "a combination of exercise, psychological, and educational interventions is the most effective form of cardiac rehabilitation."
Cochrane Collaboration Review of Exercise-Based Rehabilitation (2001)
The Cochrane meta-analysis of exercise-based rehabilitation for coronary artery disease (CAD) was based on 8440 patients in hospital and community settings following AMI (majority of participants), CABG or PTCA, or angina or CAD defined by angiography. Primary conclusions included that: (1) exercise-only intervention reduced total cardiac mortality by 31%; (2) comprehensive cardiac rehabilitation reduced total cardiac mortality by 26%; (3) neither intervention had any effect on the occurrence of non-fatal myocardial infarction; and (4) total cholesterol of patients participating in comprehensive programs was reduced significantly. 7
Taylor, et al.'s (2004) Review and Meta-Analysis of Exercise-Based Rehabilitation

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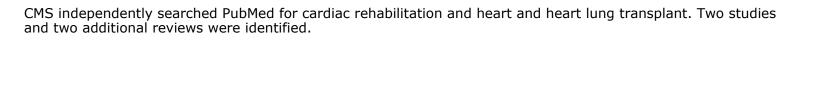


Stewart, et al. (2003) reviewed the evidence for comprehensive exercise-based cardiac rehabilitation programs following percutaneous revascularization and reported that "percutaneous interventions are effective for interrupting the process of acute coronary stenosis. Although it is fortunate that myocardial tissue damage can be avoided or minimized if the patient is treated in a timely manner, the need to treat the underlying disease that precipitated the stenosis is not changed after a revascularization procedure." The review further noted that despite the expanded use of percutaneous revascularization, there are few controlled studies of cardiac rehabilitation after these procedures. In one study, 93 patients who had been treated with percutaneous transluminal coronary angioplasty were randomly assigned to receive a behaviorally oriented intervention or to a control group [Lisspers, et al. 1999]. After 12 months, the intervention patients, compared with the control subjects, improved significantly on self-rated measures of smoking, exercise, and diet habits. Patients also lost weight, improved their exercise capacity, and experienced less chest pain during exertion. Although the mechanisms for decreased mortality with exercise have not been fully explained, exercise training improves the lipid profile, reduces blood pressure, lowers the fasting glucose level, and reduces body fat and increases lean body mass...." Therefore, "risk factor management is no less critical for these [PTCA] patients than for those with other manifestations of atherosclerosis, even in the absence of myocardial damage, and may lead to a slowing of coronary disease progression."16

Belardinelli, et al. (2001) reported an RCT of 118 consecutive patients with CAD (mean age = 57 ± 10 years) who underwent PTCA or stenting on one (69%) or two (31%) coronary arteries. Patients were randomized into either a training group (49 men and 10 women, mean age = 53 ± 11 years) who exercised 3 times a week for 6 months at 60% of peak VO₂, or a control group (50 men and 9 women, mean age = 59 ± 10 years) who were recommended to perform daily mild physical activities but to avoid physical training. Results showed that only trained patients had significant improvements in peak VO₂ (26% increase, p < 0.001) and quality-of-life (26.8% increase, p = 0.001) versus controls. The angiographic restenosis rate was unaffected by exercise training and was not significantly different after either PTCA or stenting. During the follow-up (33 ± 7 months), trained patients had a significantly lower event rate (e.g., new AMI, angioplasty or CABG) than controls (11.9 vs. 32.2%, RR 0.71, 95% CI: 0.60-0.91, p = 0.008) and a lower rate of hospital readmission (18.6 vs. 46%, RR 0.69, 95% CI: 0.55-0.93, p < 0.001).17

Dendale, et al. (2005) retrospectively reported a cohort of 223 Dutch post-PCI patients "none of whom had experienced a cardiac event in the 3 years before PCI was performed." The training group (107 men and 33 women, mean age = 62 ± 7 years) consisted of those patients who participated in the entire 3 month multidisciplinary cardiac rehabilitation program offered by one hospital's cardiologists, and the control group (54 men and 29 women, mean age = 68 ± 8 years) were patients referred to the hospital's cath lab from an outside institution where no structured rehabilitation was offered. Results showed that the incidence of total major adverse cardiac events in the rehabilitation group was lower (24% versus 42%, p = 0.005) than in the controls. There was no significant between-group difference in myocardial infarction (3% versus 2%), but the incidences of documented restenosis (14% versus 23%, p <0.005), recurrent angina (7% versus 20%, p < 0.005), need for revascularization (17% versus 30%, p < 0.005) and death (1% versus 6%, p < 0.05) were all significantly lower in the rehabilitation group compared to controls. The only risk factor significantly different between groups was hypercholesterolemia, which was present in 61% of rehabilitation patients and 85% of controls (p < 0.005).

Heart or Heart Lung Transplant



In 2005, Kavanagh published a review of exercise rehabilitation for cardiac transplant patients. 19 The author noted: "The routine use of a comprehensive exercise rehabilitation program following heart transplantation improves exercise capacity, permits bouts of submaximal effort for longer periods and with less fatigue, improves muscle mass and function, and ameliorates steroid-induced osteoporosis. While maximizing the benefits of surgery, it is unlikely that it can completely restore physiological function. The prescription of exercise must take into account the denervated heart's peculiar response to effort and must place heavy reliance on perceived exertion and metabolic measurements rather than on target heart rates for defining the intensity of training."20

In 2003, Stewart and colleagues discussed the scientific and clinical evidence for cardiac rehabilitation in patients who underwent heart transplant. The authors noted: "Although the studies reviewed are small, there is sufficient evidence that cardiac rehabilitation improves physiologic hemodynamic responses and helps to preserve or reverse bone and muscle loss (Table 1). Dealing with the continued medical consequences of cardiac transplantation is challenging, and the multidisciplinary nature of cardiac rehabilitation, including exercise, education, nutrition, and behavioral interventions, is ideally suited to these patients. One study reported that heart transplantation in selected patients who were ≤ 70 years of age could be performed with similar morbidity, mortality, and intermediate-term survival as found in younger persons. Although the efficacy of cardiac rehabilitation for elderly heart transplant patients has not been studied, it would be expected that the same benefits as demonstrated in younger persons would result in these patients." $\frac{22}{100}$

In 2003, Kavanagh and colleagues published the results of a case control study on exercise capacity following heart transplant. Thirty six cases were enrolled and received 16 months of outpatient exercise training which involved walking, progressing to jogging if tolerated, initially a distance of 1.6 km 5 times weekly. All patients completed the program. The final assessment was performed an average of 12 years after the program. Of the 36 men, 20 were evaluated. Mean age was 48 years. Thirteen patients had died and 3 were lost to follow up. At 16 months, there was a significant increase of 26% on average in peak oxygen intake, as measured by progressive cycle ergometry test. Over the follow-up period, "gains in exercise capacity are lost over 12 years at a rate commensurate with normal aging." In this study, univariate and multivariate analyses were used. Controls were age matched men who were not regularly exercising and used to establish changes with aging.



In 2004, Austin and colleagues reported the results of a trial to "to determine whether a cardiac rehabilitation programme improved on the outcomes of an outpatient heart failure clinic (standard care) for patients, over 60 years of age, with chronic heart failure." Heart failure was defined as New York Heart Association class II or III, left ventricular systolic dysfunction (ejection fraction \geq 40%), confirmed by echocardiography. The primary endpoints were functional status (NYHA class I–IV), functional performance (6-minute walk test), perceived exertion (Borg Rating of Perceived Exertion), and health-related quality of life in terms of disease specific (Minnesota Living with Heart Failure survey) and cost utility (EuroQol - European Qualify of Life index) questionnaires. Two hundred patients were randomly assigned to cardiac rehabilitation (N=100) or standard care (n=100). The program consisted of an 8 week rehabilitation program, educational sessions, and counseling. Patients had sessions two times per week for 2.5 hours. After the initial 8 weeks, patients had weekly 1 hour sessions for 16 weeks. At the 24 week follow-up, the authors noted "significant improvements in MLHF and EuroQol scores, NYHA classification and 6-minute walking distance (meters) at 24 weeks between the groups (p<0.001)." In this study, the exercise was not specifically reported. A clinical nurse specialist coordinated the exercise.

In 2004, van den Berg-Emons and colleagues reported the results of a clinical trial "to assess whether aerobic training leads to a more active lifestyle and improved quality of life (QoL) in patients with CHF." $\frac{30}{2}$ Patients with stable heart failure, NYHA class II or III, and ejection fraction < 40% were included. Thirty-four patients were randomly assigned to training (n=18) or control (n=16) groups. Training consisted of cycling, walking and aerobic games and was performed 2 times per week for 1 hour. Mean age was 59 years. Men comprised 74% of the study population. After 3 months, there were no significant changes in lifestyle and quality of life. The authors concluded that "at group level training did not result in a more active lifestyle or improved QoL." $\frac{31}{2}$

The Heart Failure – A Controlled Trial Investigating Outcomes of Exercise Training (HF-ACTION) is a large ongoing trial funded by NIH to examine the effects of exercise training on mortality and morbidity of patients with heart failure. It aims to enroll 3000 patients at 70 U.S., Canadian, and European sites. The primary hypothesis is that "exercise training in patients with LV systolic dysfunction will reduce the combined primary end point of all cause deaths and hospitalizations by 20% over 2 years vs. a usual-care group." Inclusion criteria included heart failure due to left ventricular systolic dysfunction, ejection fraction \geq 35%, NYHA class II-IV, and stable optimal medical therapy. The exercise program consists of treadmill or bicycle exercise three times a week for the first 3 months at the participating site. 34

In 2005, Ko and McKelvie reported the findings of a systematic review of exercise training in patients with heart failure. The authors noted: "Heart failure (HF) is characterized by dyspnea and fatigue leading to exercise intolerance. HF patients have been advised to avoid exercise because of concerns about detrimental cardiac effects. However, in many studies on the effects of exercise training, HF patients have demonstrated beneficial outcomes. Furthermore, exercise training has been found to be safe. Recent studies have demonstrated that exercise training might reduce morbidity and mortality. Although these data are promising, confirmation is required from a large clinical trial powered to examine the effect of exercise training on morbidity and mortality."³⁵

In 2005, Delagardelle and Feiereisen reported the findings of a systematic review of strength training for patients with chronic heart failure. The authors noted: "Due to the specific loss of muscular mass, function and strength in advanced CHF, application of strength training should be considered as a logical answer to address muscle wasting. Strength training has to be applied by well trained therapists in an adapted infrastructure and regular supervision of the patients has to be provided. Actual recommendations state that strength training should only be applied in hospital or rehabilitation centres and that careful, individually adapted programs are needed. Adequate training of therapists is required to promote strength training on a larger scale.

Strength training can add to the quality of life of CHF patients as their daily life activities are often limited by the loss of muscular strength. It further improves balance, reducing falls and increases bone density in those (often old-aged) patients. For the moment, large trials are lacking, especially because training is not as largely funded as other therapeutic interventions in CHF like new drugs or resynchronization therapy. Thus it is difficult to compare the effects of training therapy to other proven therapeutic options. As CHF is a disease which is also very frequent in countries where expensive therapeutic options cannot be afforded, training therapy should be recommended and promoted by the world wide cardiology community."³⁶

In 2004, Rees and colleagues presented the findings of a Cochrane review on exercise based rehabilitation for heart failure. They reported: "Exercise training improves exercise capacity and quality of life in patients with mild to moderate heart failure in the short term. One study found beneficial effects of exercise on cardiac mortality and hospital readmissions over 3 years of follow-up, the remaining included studies did not aim to measure clinical outcomes and were of short duration. The findings of the review are based on small-scale trials in patients who are unrepresentative of the total population of patients with heart failure. Other groups (more severe patients, the elderly, women) may also benefit. Large-scale pragmatic trials of exercise training of longer duration, recruiting a wider spectrum of patients are needed to address these issues."37

In 2004, the ExTraMATCH collaborative group reported the results of a meta-analysis to determine the effect of exercise training on survival in patients with heart failure. Randomized controlled trials of exercise training for at least eight weeks with individual patient data on survival for at least three months were included. Nine studies through 2002 with 801 patients (395 exercise training, 406 controls) were reviewed. The primary outcome was death from all causes. The authors found that "during a mean (SD) follow up of 705 (729) days there were 88 (22%) deaths in the exercise arm and 105 (26%) in the control arm" (hazard ratio 0.65, 95% confidence interval, 0.46 to 0.92). They concluded: "Meta-analysis of randomised trials to date gives no evidence that properly supervised medical training programmes for patients with heart failure might be dangerous, and indeed there is clear evidence of an overall reduction in mortality. Further research should focus on optimising exercise programmes and identifying appropriate patient groups to target." Patients with the exercise training programmes and identifying appropriate patient groups to target.

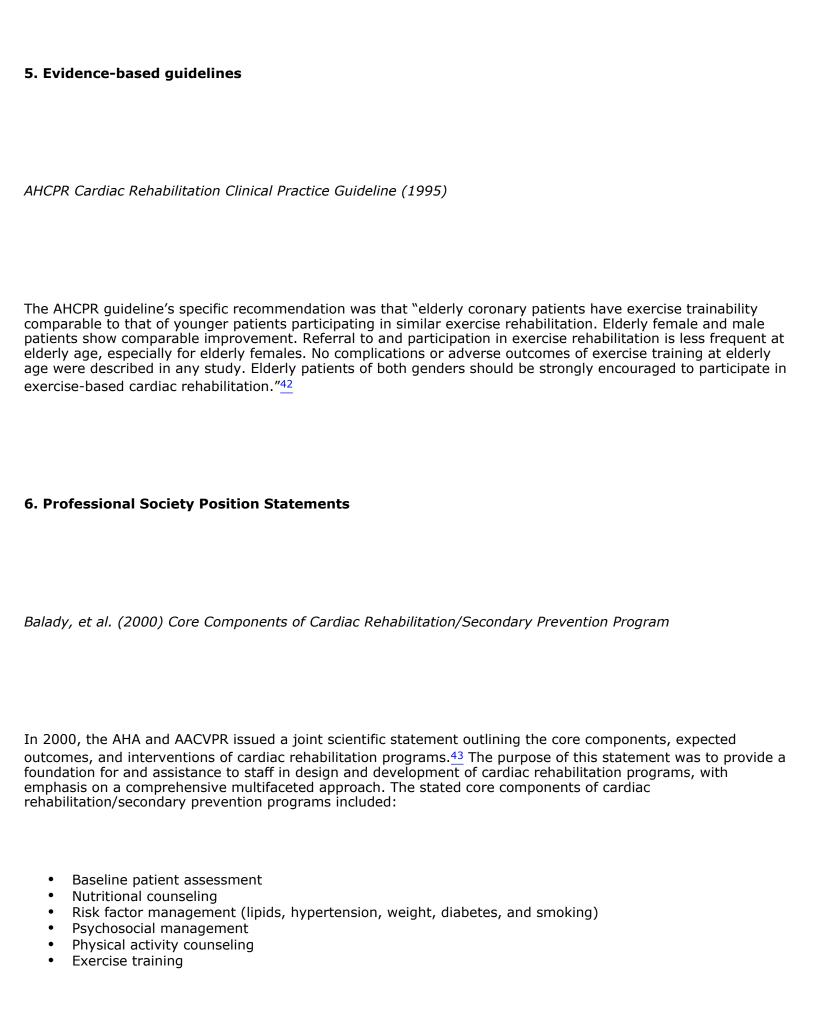
In 2003, Stewart and colleagues discussed the scientific and clinical evidence for cardiac rehabilitation in patients with CHF. 40 They noted: "Patients with heart failure often experience fatigue and dyspnea with exertion. Although the primary pathology of heart failure results from abnormalities in cardiovascular function, abnormalities in peripheral blood flow, skeletal muscle morphology, metabolism, strength, and endurance all contribute to the heart failure syndrome. Several trials have shown that cardiac rehabilitation improves disease-related symptoms, quality of life, and clinical outcomes. Overall, prescribed exercise attenuates the fatigue and dyspnea that limit exercise intolerance. The improvements ranged from 15 to 30% in peak VO2, which is greater than or equal to the gains in exercise capacity observed in many clinical drug trials."41

4. MCAC

A meeting of the Medicare Coverage Advisory Committee entitled *Physician-supervised behavioral interventions* for patients with symptomatic coronary artery disease (CAD) was held in January 2005. Meeting materials and detailed information are available at http://www.cms.hhs.gov/mcd/viewmcac.asp?where=index&mid=27. The MCAC only reviewed evidence for symptomatic coronary artery disease and did not evaluate all of the requested indications in this NCA.

In summary, a technology assessment provided evidence that secondary prevention programs improve processes of care, enhance quality of life/functional status, reduce hospitalizations, and reduce long-term mortality in patients with established CAD. The weight of the published randomized trial evidence suggests that comprehensive secondary prevention programs positively impact on processes of care (risk factor profiles, use of proven efficacious therapies) which are closely linked to subsequent morbidity and mortality in patients with CAD. Pooling the data from those trials which reported subsequent rates of MI does reveal a trend towards reduction in recurrent MIs over a median follow-up of 12 months; the majority of these programs also demonstrate improved symptom scores, exercise tolerance, or quality of life in participants. The mortality benefit derived from participation in the secondary prevention programs was apparent with longer lengths of follow-up. There was a statistically significant 15% reduction in hospitalizations.

The panel voted to inform CMS that for the purpose of the panel's recommendations, physician-supervised behavioral interventions refer to interventions that are comprehensive, intensive and multidisciplinary. On the question of how well the evidence addresses the effectiveness of physician-supervised behavioral interventions for patients with symptomatic CAD as compared to usual medical/surgical management, the panel voted that the evidence was reasonably well. On the question of how well the evidence addresses the effectiveness of physician-supervised behavioral interventions for patients with symptomatic CAD the panel voted that they were moderately to highly confident in cases of cardiac event including angina, long-term survival, short-term survival and quality of life. Concerning the likelihood that the therapy would produce a clinically important net health benefit in the treatment of patients with symptomatic CAD, the panel voted that they were moderately to highly confident that it would and that, based on the evidence, they were moderately confident that the results could be generalized to the Medicare population (aged 65+).



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AHA Statement: Secondary	Prevention of Coronary	Heart Disease	in the Flderly i	(2002)

With particular emphasis on patients \leq 75 years of age, this AHA statement concluded that "secondary prevention interventions to impact and control risk factors in older patients with CHD, including habitual cigarette smoking, hypertension, abnormal blood lipids, elevated blood glucose, obesity, various psychological concerns, and physical inactivity, appear effective to an extent similar to that observed in younger patients. Greater involvement of the elderly in these programs is needed to fully realize the therapeutic and secondary preventive potential."

In its section on management of prescribed exercise for increasing activity and fitness, the AHA statement noted that "modification of the components of the exercise prescription should be considered for elderly patients, particularly those \geq 75 years of age and those with significant comorbidities that limit mobility, e.g., arthritis, pulmonary disease, and peripheral arterial disease. Increasing caloric expenditure and enhancement of functional mobility should be emphasized, as well as participation in activities that increase socialization with others. The latter is paramount to combating feelings of isolation and depression. Increasing frequency and duration of exercise sessions should supersede increases in intensity and progression to reduce the potential for overuse injuries. Strength training for elderly patients as a component of the overall exercise prescription should improve neuromuscular function, muscular strength, and endurance. Such training is essential to improving responses to the various physical demands of daily living as well as occupational and recreational activities. Furthermore, it is likely to improve functional independence and self-esteem, while reducing the risk of injury associated with musculoskeletal overuse and falls."⁴⁴

AHA Statement: Cardiac Rehabilitation and Secondary Prevention of CHD (2005)

In 2005, the AHA updated its 1994 scientific statement on cardiac rehabilitation, reviewed the core components for effective rehabilitation/secondary prevention programs, and provided detailed research recommendations. In 1994, for example, the AHA carefully noted that the body of literature was clearly lacking with respect to studies on specific populations, e.g., women, elderly, and minorities. In 2005, the AHA noted that evaluations were still needed "to determine the effectiveness and safety of a variety of approaches designed to increase patient referrals, accessibility, and delivery of cardiac rehabilitation and secondary prevention services and to promote adhere to program components..." In its 2005 statement, the AHA also reinforced and recommended that "randomized trials are needed to better define the role of exercise therapy for safely improving functional capacity, reducing cardiovascular symptoms, and enhancing the quality of life among specific subgroups of CVD patients, particularly older, female, and ethnic minority patients..."45

Professional Society Public Comments

During the initial 30-day comment period, CMS received comments from seven professional societies, the AHA, the American College of Cardiology (ACC), the AACVPR, the American College of Sports Medicine (ACSM), the American Physical Therapy Association (APTA), the Iowa Hospital Association, and the Illinois Hospital Association. The full text of these comments can be found at http://www.cms.hhs.gov/mcd/viewpubliccomments.asp?nca_id=164.

Clinical Evidence - General

The American Physical Therapy Association provides general clinical evidence to support cardiac rehabilitation. They cite several reviews, studies and clinical trials which showed improvements in exercise capacity, cardiac risk factors, hospital admissions rates and quality of life in elderly patients after participating in cardiac rehabilitation programs, thus demonstrating the benefit of cardiac rehabilitation, especially when combined with education and lifestyle modification.

Clinical Evidence for Acute MI

The AHA, AACVPR, ACC, and ACSM cite meta-analyses, studies, reviews, and trials which demonstrate the benefit of cardiac rehabilitation in patients who experience acute AMIs. Specifically these patients experience significant decreases in mortality, decreases in recurrent AMIs, an overall survival benefit in women and patients over age 70, improvements in physical function and performance of activities of daily living with programs including resistance training, and decreases in physical disability.

Clinical Evidence for Post CABG

The AHA, AACVPR, ACC, and ACSM cite numerous studies which have demonstrated the ability of cardiac rehabilitation programs to improve functional capacity in patients ages 65 and older, especially in patients who undergo CABG surgery who are considered severely disabled. They acknowledge, however, that evidence of a benefit due to cardiac rehabilitation was less clear in older subsets of patients after CABG surgery. They refer to a controlled trial involving cardiac rehabilitation after CAGB surgery with a 10 year follow up which documented a reduction in hospital readmissions and cardiovascular events. A second study showed that improvements in exercise capacity were correlated with a decrease in long term mortality rates of patients after CABG surgery and AMI, following participation in a cardiac rehabilitation program.

Clinical Evidence for Stable Angina

The AHA, AACVPR, ACC, and ACSM cite an article and study to demonstrate the benefit of exercise training in improving exercise tolerance in patients experiencing chronic stable angina pectoris and in increasing functional capacity and reducing coronary events as compared to patients who underwent invasive PCI.

Clinical Evidence for Post Heart Valve Replacement

The AHA, AACVPR, ACC, and ACSM cite a 2003 article which establishes that available data for patients who have undergone heart valve surgery supports improvements in physiological functioning and quality of life due to participation in cardiac rehabilitation programs. They also cite a 1991 statement by the AHCPR confirming that cardiac rehabilitation programs are beneficial in patients who have undergone cardiac valve surgery. These organizations cite studies that reveal that before cardiac valve surgery, most patients have very low exercise capacities with cardiovascular characteristics similar to heart failure patients. Their comments refer to studies which further support the benefit of cardiac rehabilitation programs in valve replacement patients showing improvements in physiological functioning, exercise capacity, and quality of life as compared to control groups especially in elderly patients as well as women after mitral valve replacement.

Clinical Evidence for Post Angioplasty

The AHA, AACVPR, ACC, and ACSM refer to findings of multiple studies and trials which associated participation in cardiac rehabilitation programs after PCI with numerous physiological improvements, decreased morbidity and hospital readmission rates, and improved quality of life. They further cite studies addressing unique physiological characteristics of the elderly, like the risk of restenosis in PCI patients, and benefits of exercise and risk reduction in improving these characteristic by slowing the progression of coronary artery disease. They also cite the importance of cardiac rehabilitation programs in identifying signs and symptoms of restenosis early and also in providing education and medical interventions to reduce the risk of future events.

These societies state that because the underlying disease process is the same in PCI patients as in other coronary patients they have the same needs for improving exercise capacity and reducing risk factors, and can experience the same benefits.

Clinical Evidence for Post Heart or Heart-Lung Transplant

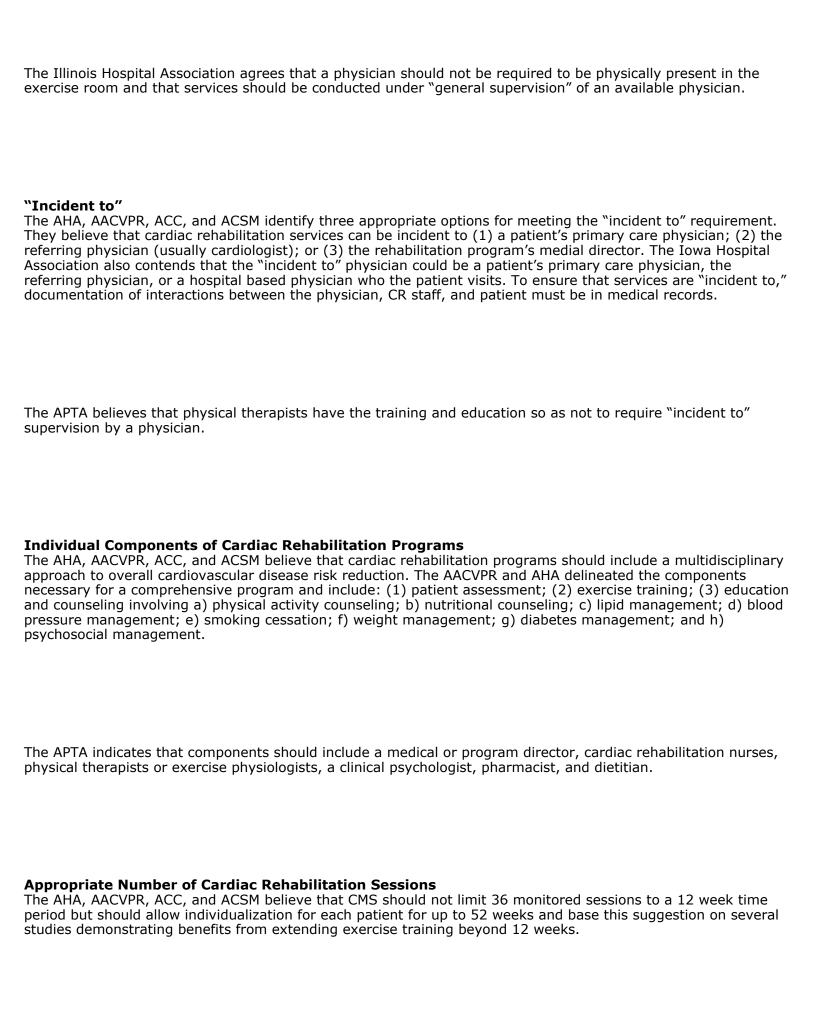
The AHA, AACVPR, ACC, and ACSM focus their attention on several studies that examined the exercise response of patients after heart transplant and found that exercise capacity is significantly reduced as compared to same age non-transplant patients.

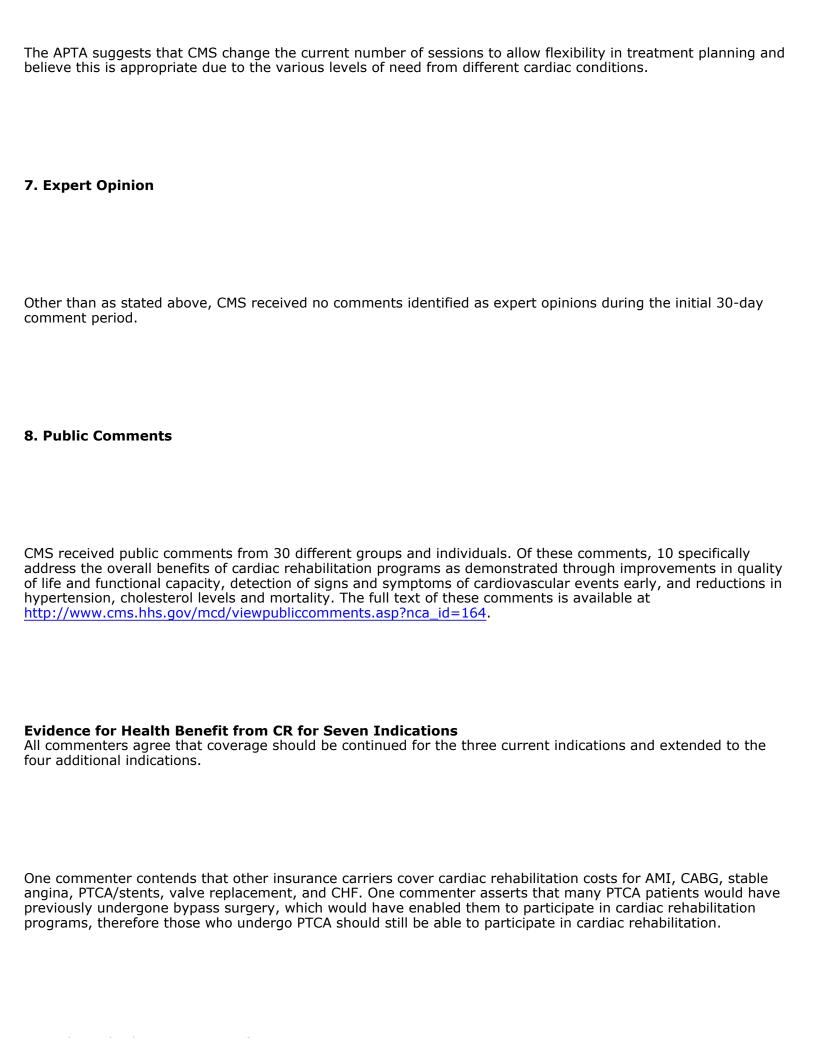
They assert that a number of studies since the early 1980's have demonstrated the potential of exercise training to reverse or diminish many physiological abnormalities observed in heart transplant patients, reported improvements in endurance capacity, increases in lean body mass, decreases in fat mass, and established the importance of resistance training to increase bone mineral density.

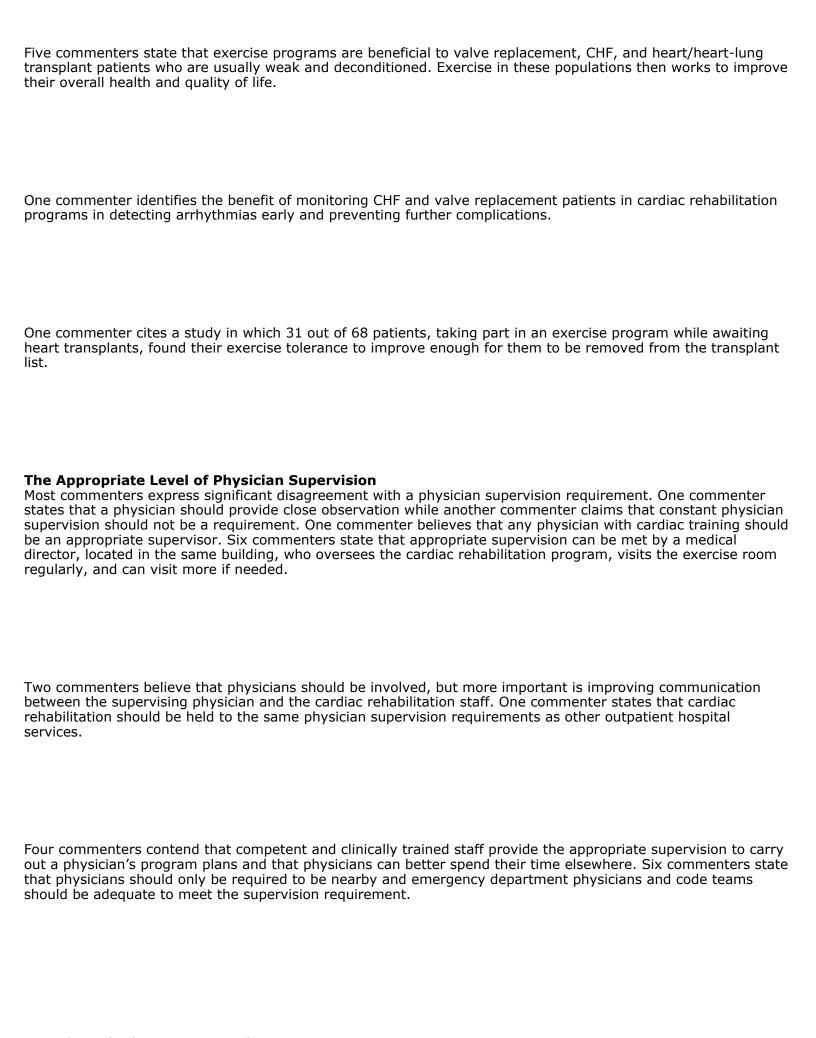
Also cited is the first randomized trial of heart transplant patients where patients randomized to a medically supervised cardiac rehabilitation program increased their oxygen uptake and peak workload significantly more than home exercise patients but revealed no difference between the groups in use of anti-hypertensive medications, number of rejections and infections, and weight gain.
Clinical Evidence for Congestive Heart Failure The AHA, AACVPR, ACC, and ACSM refer to more than two dozen controlled trials which have assessed the effects of exercise training in CHF patients, most age 65 and older, with each trial demonstrating the benefit of exercise n reducing fatigue and improving exercise capacity. In various studies, improvements in shortness of breath, ability to perform activities of daily living, anxiety, depression, and well-being were observed as well as mprovements in left ventricular ejection fraction and reverse remodeling.
The societies go on to cite the European Heart Failure Training Group's report that no adverse exercise training-related side effects were reported in the results from randomized controlled trials at seven separate centers, nvolving 134 CHF patients and note that physician involvement to monitor, evaluate, and care for complications, was required in the heart failure exercise trials to date. They also refer to a 2002 trial that reported no exercise training-related effect on clinical outcomes.
Appropriate Level of Physician Supervision The AHA, AACVPR, ACC, and ACSM state that the current coverage requirements contradict the Medicare Intermediary Manual requirements at 3112.4 A, which states that the physician supervision requirement is assumed to be met when services are performed on hospital premises. They suggest removing the requirement that a physician be in the area of the exercise room for hospital-based programs due to a lack of clinical basis for such requirement. The Iowa Hospital Association's comments closely reflect these.
The four societies believe that when cardiac rehabilitation is provided in a physician's office or outpatient facility requiring immediate availability of a physician is reasonable. They suggest two levels of physician supervision: (1) program medical director overseeing the program but not required to be physically present; and (2) remergency supervision/consultation from the emergency department staff and a "code" team.

The APTA believes that physician supervision of physical therapy services in cardiac rehabilitation programs should not be required because Congress has defined these services without requiring physician supervision for independent practitioners in Section 1861 of the Social Security Act, and physical therapists' education, clinical training, and licensing requirements qualify them to provide cardiac rehabilitation services.

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Finally, 10 commenters express their concerns that a direct physician supervision requirement would place a great burden on small and rural healthcare facilities potentially causing cardiac rehabilitation programs to close and thus significantly limit patient access to cardiac rehabilitation services.

To Which Physician Should Services be "Incident To"

The commenters express various positions regarding to which physician cardiac rehabilitation services should be "incident to." One commenter states that the "incident to" physician should be a cardiologist, another commenter states that the physician should be the physician supervising cardiac rehabilitation services, and one commenter states that the "incident to" physician could be either a cardiologist or the cardiac rehabilitation "medical director." Two commenters explain that services should be "incident to" the referring physician, preferably a cardiologist or the patients' primary care physicians, while another commenter asserts that services should not be "incident to" the referring physician in order to avoid complications and increases in cost. Finally, two commenters maintain that services should be "incident to" any physician, and one commenter states that services should be "incident to" the hospital-clinic provider.

Individual Components of Program

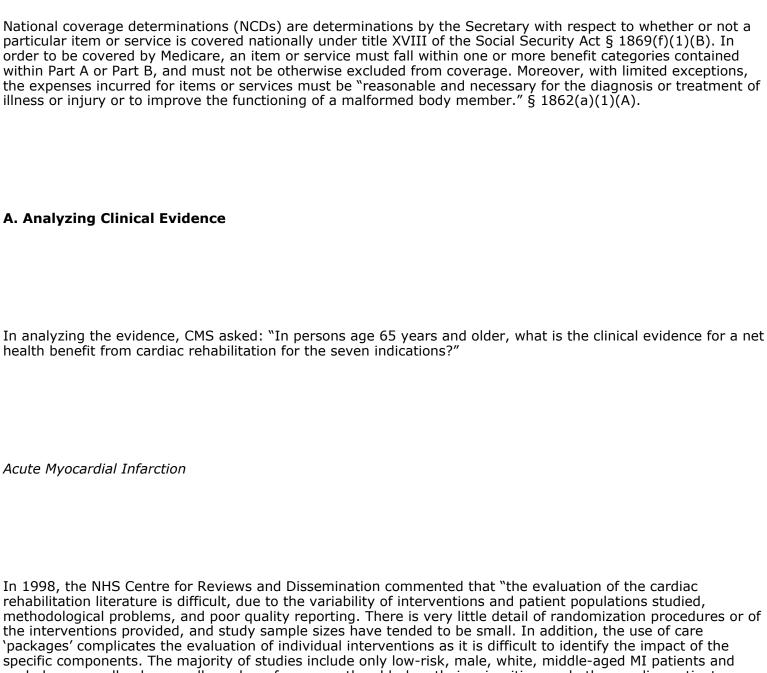
Eight commenters agree that individualized education addressing nutrition, medication, stress and disease management, and lifestyle changes is a necessary component of cardiac rehabilitation programs. Five commenters stress the importance of individualized exercise programs which account for each patient's level of conditioning and contraindications and one commenter identified the importance of monitoring patients' physiological response to exercise.

One commenter identifies the initial assessment as an important component. One commenter cites social support from other patients as an important component. One commenter recognizes the use of established community programs as an important component.

Appropriate Number of Rehab Sessions

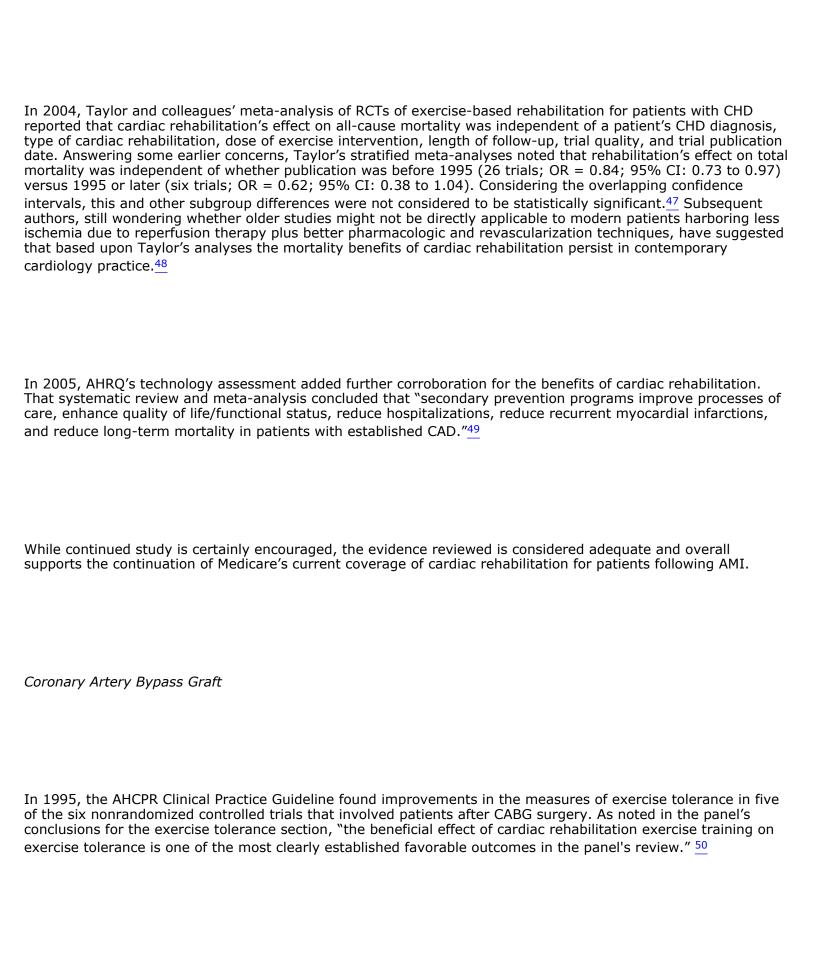
In addressing the appropriate number of cardiac rehabilitation sessions needed to achieve a net health benefit, five commmenters contend that an average of 36 sessions is appropriate to allow patients' to meet their goals. Five other commenters argue that the number of sessions should be individualized and depend on each patient's level of conditioning and individual goals.

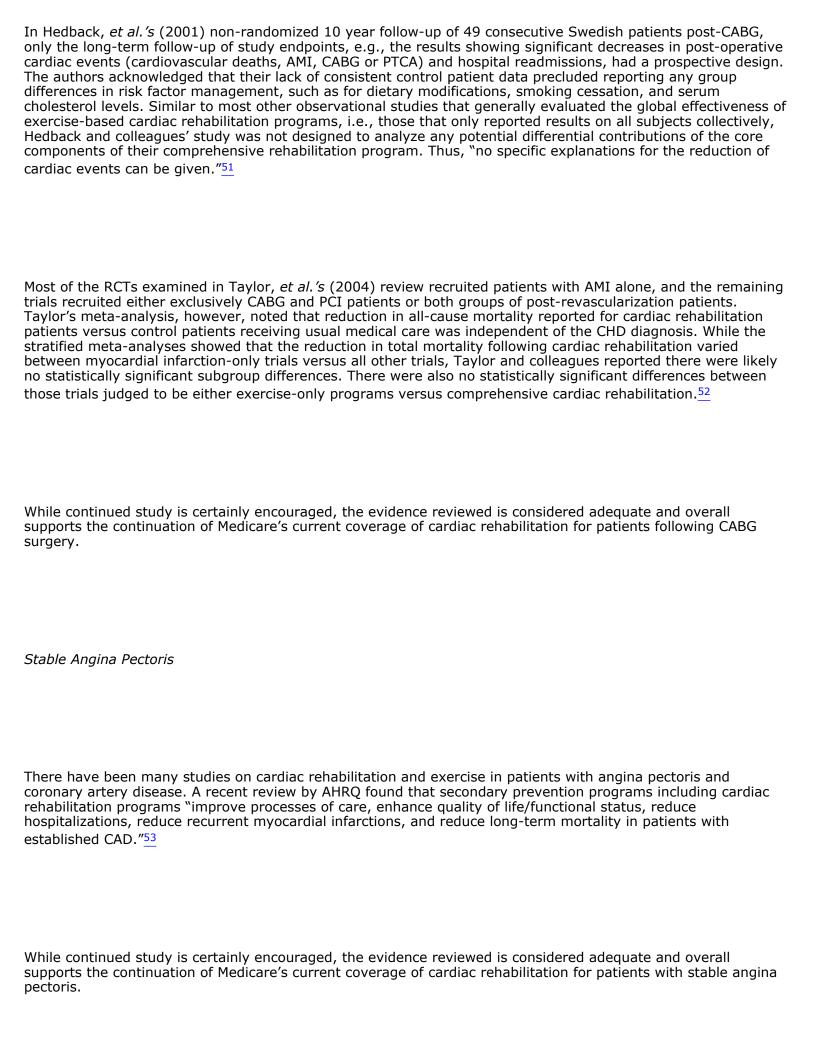
VIII. CMS Analysis



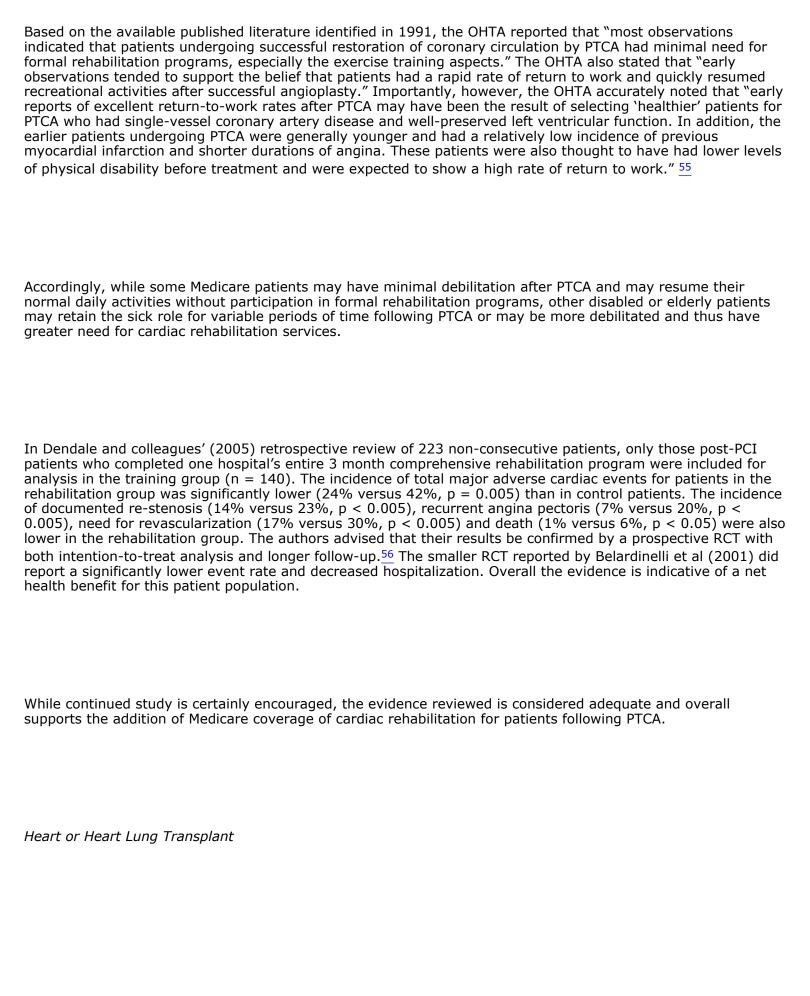
rehabilitation literature is difficult, due to the variability of interventions and patient populations studied, methodological problems, and poor quality reporting. There is very little detail of randomization procedures or of the interventions provided, and study sample sizes have tended to be small. In addition, the use of care 'packages' complicates the evaluation of individual interventions as it is difficult to identify the impact of the specific components. The majority of studies include only low-risk, male, white, middle-aged MI patients and exclude, or enroll only a small number of, women, the elderly, ethnic minorities, and other cardiac patient groups such as those following cardiac surgery, heart failure or heart transplantation, thereby limiting the generalizability of the results."46

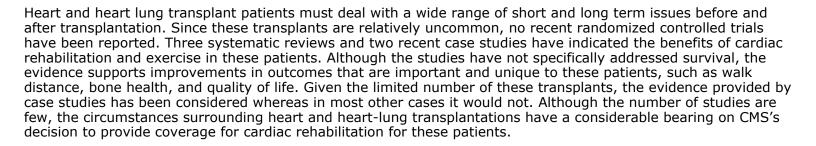
While both the NHS (1998) and Cochrane Collaboration (2001) reviews reported that exercise-based cardiac rehabilitation was effective in reducing cardiac mortality, it was unclear whether an exercise-only program or comprehensive cardiac rehabilitation was more beneficial. Most of the 27 further RCTs included in Cochrane's 2001 review were published since its original meta-analyses in the late 1980s, and Cochrane's 2001 review postulated that differences between programs may have been due to different medications taken during the trials. While details were not always given, none of patients in the five new trials in the exercise-only analysis appeared to have received statins, less than 50% (where stated) were on β blockers, and the Cochrane reviewers were unable to determine if thrombolysis was given on admission. Although more patients appeared to have been prescribed statins or β blockers, there were reportedly few details regarding medications or thrombolysis in the 15 new trials (8 published since 1995) included in this comprehensive cardiac rehabilitation intervention analysis.





Heart Valve Repair or Replacement
Based on the available published literature in 1991, the OHTA stated that "it would seem that rehabilitation programs, both in and out of the hospital, are beneficial to patients who have had cardiac valve surgery and have the potential but lack the necessary functional capacities to resume normal daily activities." The OHTA report also discussed that the necessity to enroll in a cardiac rehabilitation program was dependent on each patient's degree of debilitation. 54
Needs, therefore, for various comprehensive cardiac rehabilitation services greatly vary dependent upon each patient's symptoms, degree of debilitation, and age. Nonetheless, many of the worldwide post-op studies of aortic and mitral valve replacement enrolled predominantly male and middle-aged patients (45-65 years). Long term durability and generalizability of reported improvements in exercise tolerance and HRQL after cardiac rehabilitation post-cardiac valvular surgery thus still require careful investigation. Such studies especially should include representative numbers of Medicare patients with co-morbidities, the old (66-75 years) and very old (>75 years), plus surgical patients with more moderate to marked levels of pre-op deconditioning and impaired LV function.
While continued study is certainly encouraged, the evidence reviewed is considered adequate and overall supports the addition of Medicare coverage of cardiac rehabilitation for patients following heart valve repair or replacement.
Percutaneous Transluminal Coronary Angioplasty





While continued study is certainly encouraged, the evidence reviewed is considered adequate and overall supports the addition of Medicare coverage of cardiac rehabilitation for patients following heart or heart lung transplant.

Congestive Heart Failure

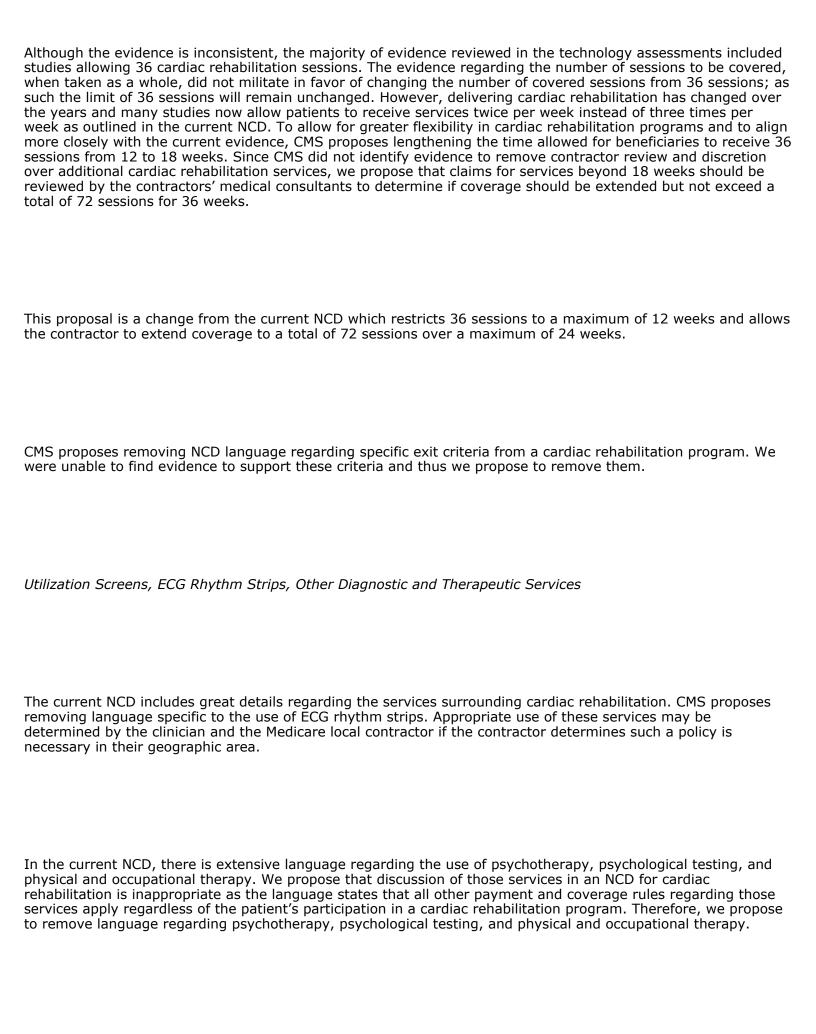
Congestive heart failure is a broad and often subjectively defined diagnosis. The New York Heart Association classification attempts to categorize the severity of symptoms but variability still exists in the type of heart failure, etiology and duration. This may create difficulties when attempting to identify the appropriate patients for inclusion into trials and the interpretation of results. In our review, there were 3 clinical trials on patients with NYHA class II or III with varying left ventricular ejection fraction criteria. Of the 3 studies, 2 (van den Berg-Emons, and Witham) did not find significant differences in their primary outcomes (more active lifestyle or improved quality of life, and 6 minute walk distance, respectively). Austin evaluated 5 outcomes (NYHA class, 6 minute walk distance, perceived exertion, quality of life and cost utility) and found promising results over baseline for these outcomes in the experimental group. However, the control group also had significant improvements in 2 of these outcomes (perceived exertion and quality of life). These findings were perplexing and may indicate some potential issues in the conduct of the trial or measurement of outcomes. There were also multiple comparisons and tests but adjustments were not made in the interpretation. The initial report by Jonsdottir suggested improvements in functional capacity, but the findings and data have not yet been published in a peer-reviewed journal so little weight can be given to this evidence at this time. Overall, the studies on CHF have enrolled a small number of patients and did not provide adequate data on the clinical outcomes of interest. None of these studies (or studies included in past analyses) were adequately designed with sufficient power to evaluate the effect of cardiac rehabilitation on mortality.

In addition to these trials, several systematic reviews were included in our analysis. All of the reviews (Ko, Delagardelle, Rees) noted the need for further evaluation. Ko and McKelvie concluded that, though the evidence was promising, confirmation was required from a large clinical trial. Delagardelle and Feiereisen's review focused on muscle wasting and strength training, rather than morbidity and mortality. Rees noted the small sample sizes and short follow-up durations as hindering the ability to draw definitive conclusions about the net health benefits for these patients. One meta-analysis (ExTraMATCH) suggested a mortality benefit, but as noted above, none of the trials included in this meta-analysis actually evaluated mortality as a primary outcome. Meta-analysis of outcomes that were not prespecified in the trials may be problematic. The ongoing HF-ACTION clinical trial was specifically designed to evaluate mortality with an estimated sample size of 3000 patients and should provide substantial, likely definitive, evidence on cardiac rehabilitation in patients with heart failure.

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The OIG report specifically notes the need for CMS to address the confusion surrounding the physician supervision requirements.
To be covered as incident to physicians' services, the services and supplies must be furnished as an integral although incidental, part of the physician's professional service in the course of diagnosis or treatment of an illness or injury. The services and supplies must be furnished on a physician's order by hospital personnel and under a physician's supervision. This does not mean that each occasion of service by a nonphysician need also be the occasion of the actual rendition of a personal professional service by the physician. However, during any course of treatment rendered by auxiliary personnel, the physician must personally see the patient periodically and sufficiently often to assess the course of treatment and the patient's progress, and where necessary, to change the treatment regimen. The physician supervision requirement is generally assumed to be met where the services are performed on hospital premises; the hospital medical staff that supervises the services need not be in the same department as the ordering physician. However, if the services are furnished outside the hospital, they must be rendered under the direct personal supervision of a physician who is treating the patient. Direct supervision is defined at 42 C.F.R. §410.26(a)(2) (defined through cross reference to 42 C.F.R. §410.32(b)(3)(ii), or 42 C.F.R. §410.27(f). Other CMS manuals may provide further guidance (e.g., Medicare Beneficiary Manual §100-2, 6-20.4.1, 15-60.1 and 15-60.3).
Incident to
The OIG also recommended that CMS clarify the requirements regarding to which physician the services must be provided "incident to." The ordering physician is the "incident to" physician.
Cardiac rehabilitation services fall under the benefit category of "incident to" a physician's professional service which requires that services be performed under direct physician supervision. In the Social Security Act (§1861(r)) a physical therapist is not included in the definition of a physician therefore supervision by a physical therapist does not satisfy the supervision requirement. Physical therapists may only provide cardiac rehabilitation services when they are providing those services under the direct supervision of a physician as defined under §1861(r).
Number of Sessions and Frequency



IX. Proposed Conclusion
CMS proposes the following:
The evidence is adequate to conclude that cardiac rehabilitation is reasonable and necessary following acute myocardial infarction (AMI), coronary artery bypass graft (CABG), stable angina pectoris, heart valve repair/replacement, percutaneous transluminal coronary angioplasty (PTCA), and heart or heart lung transplant
CMS has determined that the evidence is not adequate to conclude that cardiac rehabilitation is reasonable and necessary for congestive heart failure, and therefore we will not cover this indication.
CMS proposes revising the language in Manual 100-3 § 20.10 to read as follows:
A – Item/Service Description
Phase II cardiac rehabilitation, as described by the U.S. Public Health Service is a comprehensive, long-term program including medical evaluation, prescribed exercise, cardiac risk factor modification, education and counseling. Phase II refers to outpatient medically supervised programs that are typically initiated 1-3 weeks after hospital discharge and provide appropriate ECG monitoring.
B – Indications and Limitations of Coverage

Medicare coverage of cardiac rehabilitation programs are considered reasonable and necessary only for patients
who (1) have a documented diagnosis of acute myocardial infarction within the preceding 12 months; or (2) have
had coronary bypass surgery; or (3) have stable angina pectoris; or (4) have had heart valve
repair/replacement; or (5) have had percutaneous transluminal coronary angioplasty (PTCA); or (6) have had
heart or heart lung transplant.

C - Program Requirements

1.

Duration

Services provided in connection with a cardiac rehabilitation exercise program may be considered reasonable and necessary for up to 36 sessions without individual review by a contractor's medical consultant. Patients generally receive 2 to 3 sessions per week for 12 to 18 weeks. Claims for cardiac rehabilitation services beyond 18 weeks should be reviewed by the contractors' medical consultants to determine if coverage should be extended but not exceed a total of 72 sessions for 36 weeks.

2.

Components

Cardiac rehabilitation programs must be comprehensive and to be comprehensive they must include a medical evaluation, a program to modify cardiac risk factors (e.g., nutritional counseling), prescribed exercise, education and counseling.

3.

Facility

The facility must have available for immediate use the necessary cardio-pulmonary emergency diagnostic and therapeutic life saving equipment accepted by the medical community as medically necessary, e.g., oxygen, cardiopulmonary resuscitation equipment, or defibrillator.

4.

Staff

The program must be staffed by personnel necessary to conduct the program safely and effectively, who are trained in both basic and advanced life support techniques and in exercise therapy for coronary disease. The program must be under the direct supervision of a physician, as defined in 42 C.F.R. §410.26(a)(2) (defined through cross reference to 42 C.F.R. §410.32(b)(3)(ii), or 42 C.F.R. §410.27(f)).

Appendix A: General Methodological Principles of Study Design

CMS divides the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the relevance of findings from individual studies to the Medicare population; and 3) overarching conclusions that car be drawn from the body of the evidence on the direction and magnitude of the intervention's risks and benefits.
The issues presented here represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has unique methodological aspects.

1. Assessing Individual Studies

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias.
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.
- Prospective (rather than retrospective) studies to ensure a more thorough and systematical assessment of factors related to outcomes.
- Larger sample sizes in studies to help ensure adequate numbers of patients are enrolled to demonstrate both statistically significant as well as clinically significant outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.
- Masking (blinding) to ensure patients and investigators do not know to which group patients were
 assigned (intervention or control). This is important especially in subjective outcomes, such as pain or
 quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by
 either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is the extent to which differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias)
- Co-interventions or provision of care apart from the intervention under evaluation (confounding)
- Differential assessment of outcome (detection bias)
- Occurrence and reporting of patients who do not complete the study (attrition bias)

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

- Randomized controlled trials
- Non-randomized controlled trials
- Prospective cohort studies
- Retrospective case control studies
- Cross-sectional studies
- Surveillance studies (e.g., using registries or surveys)
- Consecutive case series
- Single case reports

When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in which confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study's selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess the evidence.

2. Generalizability of Clinical Evidence to the Medicare Population



evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our

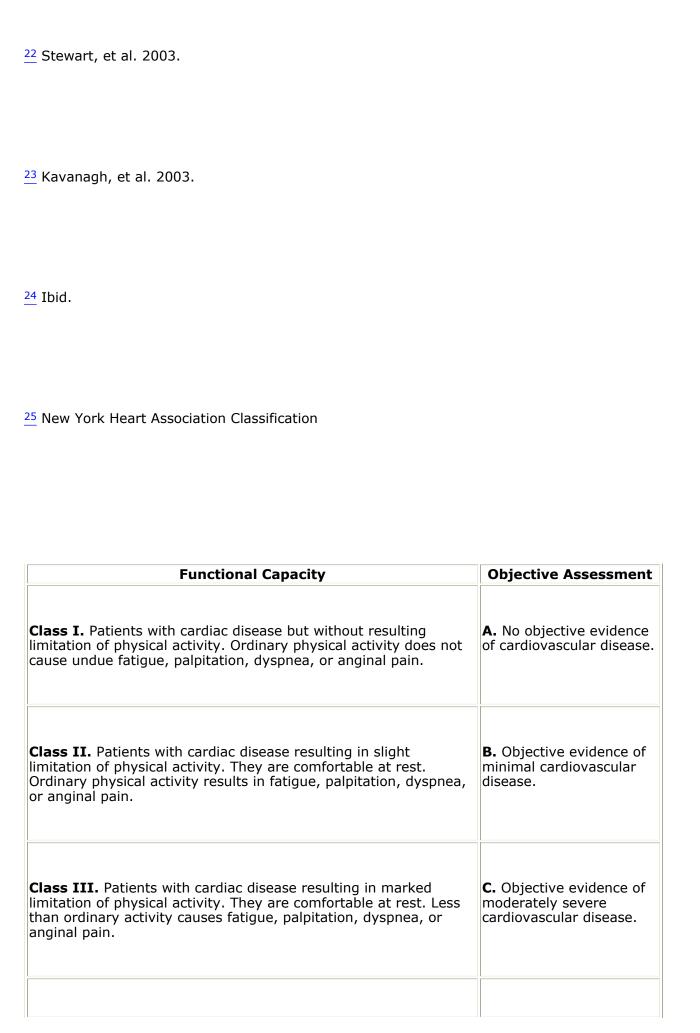
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outcomes of interest.

3. Assessing the Relative Magnitude of Risks and Benefits Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits. For most determinations, CMS evaluates whether reported benefits translate into improved net health outcomes. CMS places greater emphasis on health outcomes actually experienced by patients, such as quality of life, functional status, duration of disability, morbidity and mortality, and less emphasis on outcomes that patients do not directly experience, such as intermediate outcomes, surrogate outcomes, and laboratory or radiographic responses. The direction, magnitude, and consistency of the risks and benefits across studies are also important considerations. Based on the analysis of the strength of the evidence, CMS assesses the relative magnitude of an intervention or technology's benefits and risk of harm to Medicare beneficiaries. ¹ Gordon et al (1997) ² Pashkow (1993) ³ Forman et al (2000) 4 Ades et al (2000) ⁵ Wenger et al (1995)



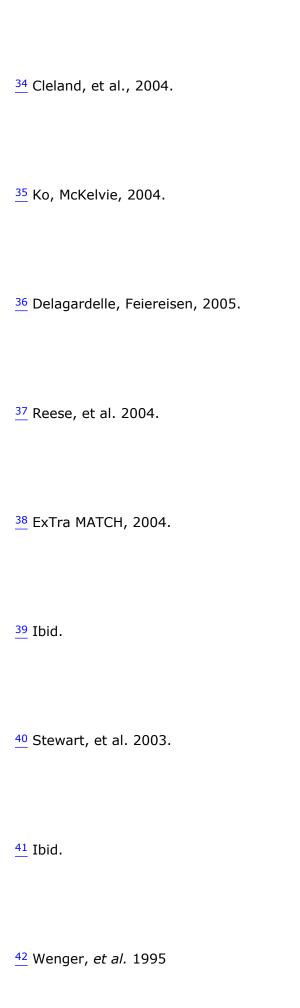




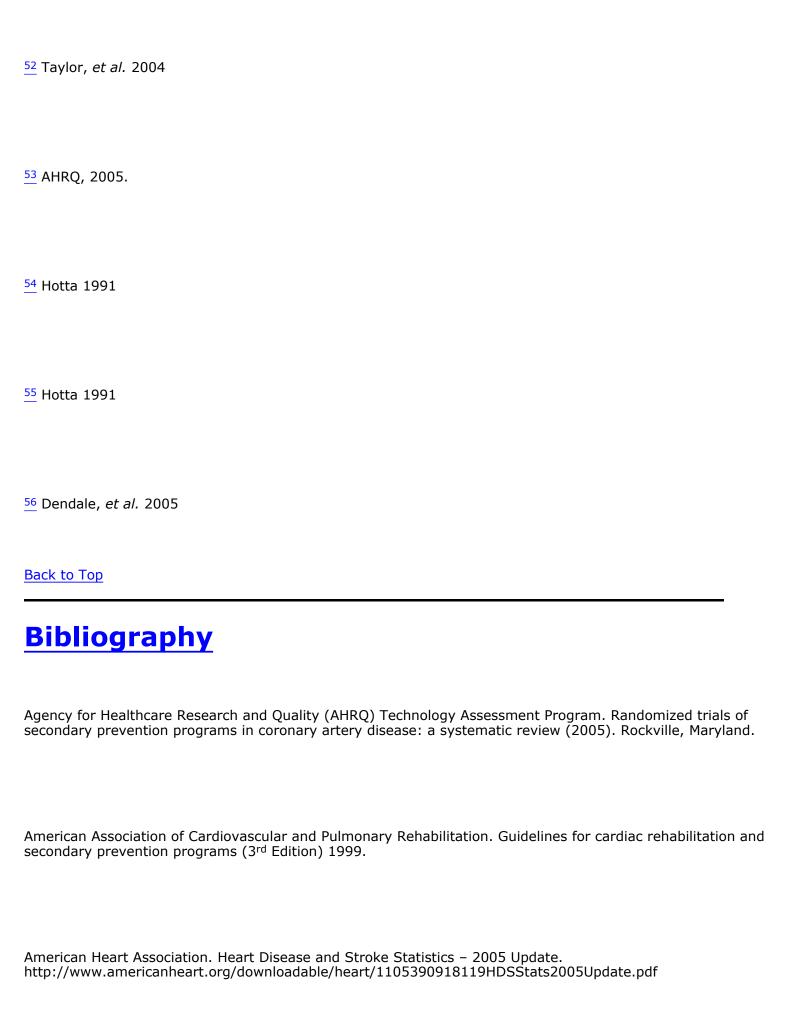
. unconstruction of participations	
Class IV. Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.	D. Objective evidence of severe cardiovascular disease.
26 Jonsdottir, et al., 2005.	
27 Witham, et al., 2005.	
28 Austin, et al., 2005.	
<u>29</u> Ibid.	
30 van den Berg-Emons, et al., 2004.	
<u>31</u> Ibid.	
32 Ko, McKelvie, 2005.	
33 Keteyian, 2005.	

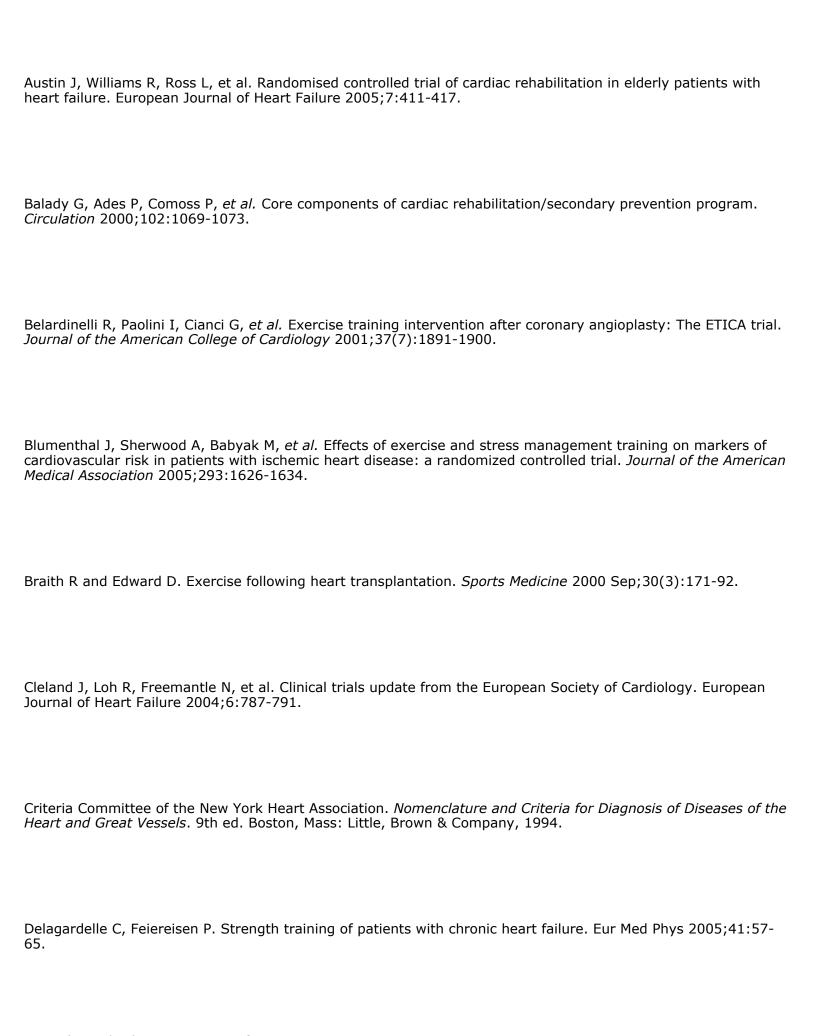
Functional Capacity

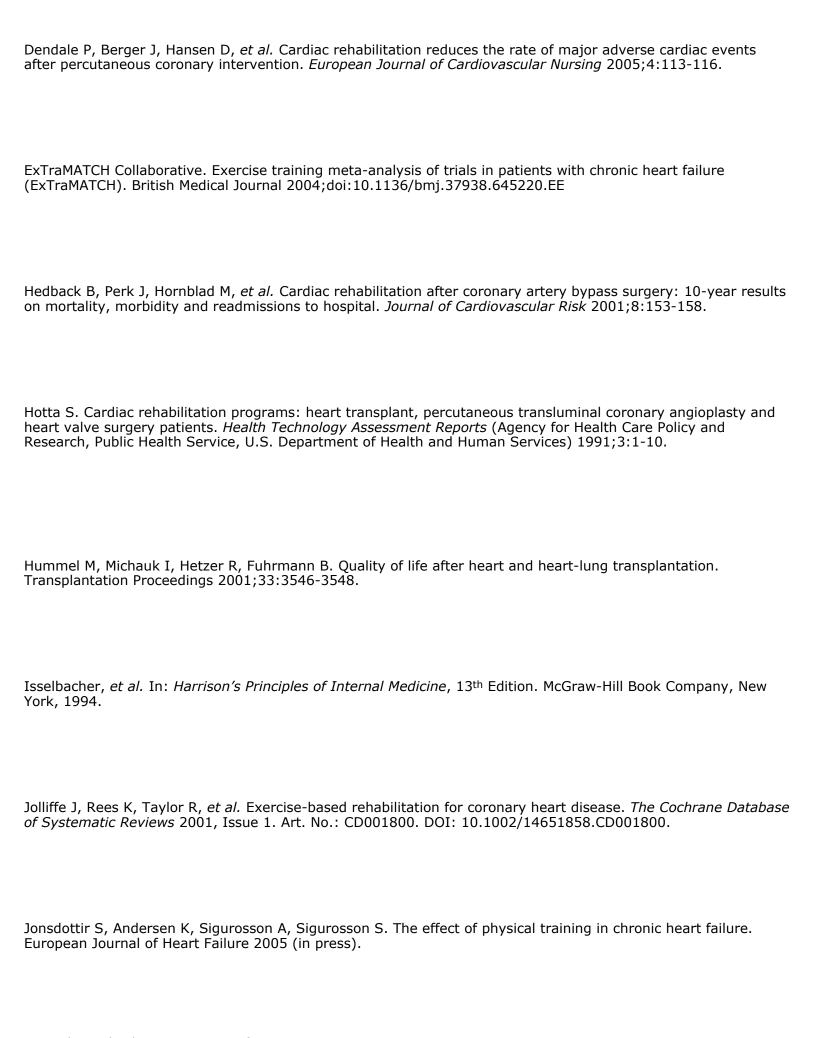
Objective Assessment

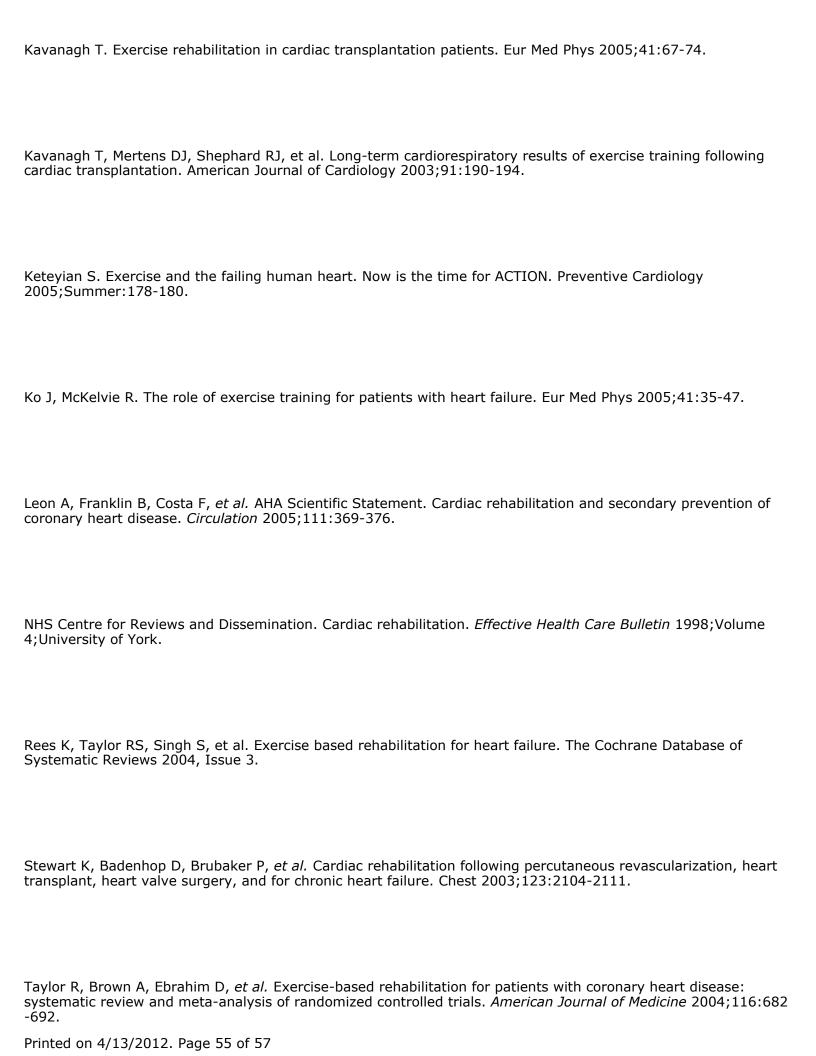


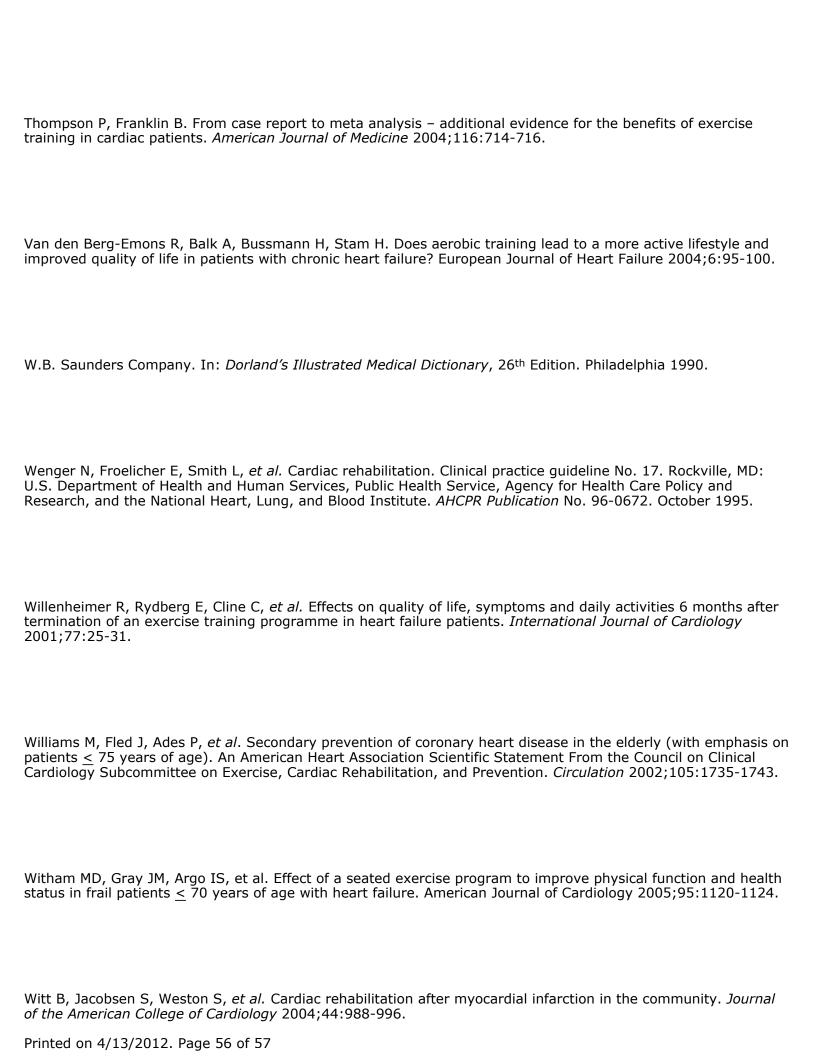












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